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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT PAPER NUMBER

1643

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/862,798

Applicant(s)

MOSER ET AL.

Examiner

Sheela J. Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/30/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 3,8,10,13,18,23,28 and 31-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-7,9,11,12,14-17,19-22,24-27,29,30 and 48-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed on 9/30/05 has been considered.

Claims 1-2, 4-7, 9, 11-12, 14-17, 19-22, 24-27, 29-30 and 48-52, as they read on antibodies and fragments thereof, are currently under consideration.

Claims 3, 8, 10, 13, 18, 23, 28 and 31-47 are withdrawn from consideration as being drawn to a non-elected invention.

### ***Response to Arguments***

#### ***Priority***

Applicant is requested to update the first line of the specification (the continuing data) to include the patent number for 09/314159.

Applicant did not respond to this.

### ***Claim Rejections - 35 USC § 112***

Claims 11-12, 14-17, 19-22, 24-27 and 29-30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant argues that some of the *Wands* factors were not considered. All of the factors have been properly considered. Specifically, applicant mentions "level of skill in

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the pertinent art". This is encompassed in "state of the art" and "predictability of lack thereof in the art".

Applicant argues that the specification discusses the humanization of antibodies. Applicant's claims are directed to the in vivo use of antibodies and fragments to inhibit angiogenesis. As clearly discussed in the rejection, applicant has not provided sufficient objective evidence to show that the in vitro assays provided by applicant can reasonably be correlated to in vivo use by one of skill in the art.

Applicant provided a paper by Moser et al. It is not clear why this paper was cited because no in vivo assays were done in the paper.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al J. Biol. Chem Vol. 250 p. 10418 (1985). The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant argues that difference in origin of ATPase (*E. Coli* vs. human) and activity. The claims are directed to monoclonal antibodies and not methods of use. To meet the limitations of these claims, the reference merely has to disclose the claimed antibody. The reference does this. Absent any objective evidence to the contrary, it is

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inherent that the monoclonal antibodies function as an angiostatin agonist, angiostatin partial agonist, angiostatin inverse agonist, angiostatin antagonist or angiostatin allosteric modulator. Furthermore, the because of the sixty percent homology any monoclonal antibody that binds to the homologous portions would clearly bind ATPase from either species.

Claims 1-2 and 4-5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al J. Biol. Chem Vol. 250 p. 10418 (1985) as evidence by applicant's definitions on pages 11-12 of the specification. The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant's argues are the same as for the above rejection. The claims are directed to compositions with intended use. Generally, intended use does not carry any patentable weight.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 4-6 and 48-52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al US 5786150 as evidence by applicant's definitions on pages 11-12 of the specification. The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant argues that the reference does not disclose that the antibody be made to the portion of ATPase that is inhibited by angiostatin. The reference clearly discloses the use of the antibodies to treat disorders including angiogenic disorders. As stated in

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the rejection, applicant defines agonist as binding the alpha or beta subunits of ATP synthase. Since the antibodies of the reference bind ATP synthase, absent any objective evidence to the contrary, it is expected that the antibodies of the reference have these functions.

Claims 1-2 and 4-5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman et al 5837682 as evidenced by applicant's definitions on pages 11-12 of the specification. The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant argues that the reference discloses the use of antibodies to reduce angiogenic inhibition. The claims are directed to compositions comprising antibodies that modulate (ie act as agonists or antagonists) angiostatin. The claims are directed to compositions with intended use. Generally, intended use does not carry any patentable weight.

Claims 1 and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al US 5786150 or Folkman et al US 5837682 in view of Allen et al US 6056973. The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant's arguments have been addressed above.

Claims 1 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al US 5786150 or Folkman et al US 5837682 in view of Masferrer et al US 6025353. The reasons for this rejection are of record in the paper mailed 12/8/04.

Applicant's arguments have been addressed above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sheela J Huff  
Primary Examiner  
Art Unit 1643

sjh